

**Introduced by Senator Stone**

February 26, 2015

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An act to amend Section 4127.1 of the Business and Professions Code, relating to pharmacy.

**LEGISLATIVE COUNSEL'S DIGEST**

SB 587, as introduced, Stone. Pharmacy: compounding.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists and pharmacy corporations in this state by the California State Board of Pharmacy. The law prohibits a pharmacy from compounding sterile drug products unless the pharmacy has obtained a sterile compounding pharmacy license from the board, and prohibits the board from issuing or renewing that license until the board has, among other things, reviewed a current copy of the pharmacy's procedures and policies for sterile compounding.

This bill would make a nonsubstantive change to that licensing provision.

Vote: majority. Appropriation: no. Fiscal committee: no.  
State-mandated local program: no.

*The people of the State of California do enact as follows:*

- 1     SECTION 1. Section 4127.1 of the Business and Professions
- 2     Code, as added by Section 5 of Chapter 565 of the Statutes of
- 3     2013, is amended to read:
- 4     4127.1. (a) A pharmacy shall not compound sterile drug
- 5     products unless the pharmacy has obtained a sterile compounding
- 6     pharmacy license from the board pursuant to this section. The
- 7     license shall be renewed annually and is not transferable.

1 (b) A license to compound sterile drug products shall be issued  
2 only to a location that is licensed as a pharmacy and shall be issued  
3 only to the owner of the pharmacy licensed at that location.

4 (c) A license to compound sterile drug products shall not be  
5 issued or renewed until the location is inspected by the board and  
6 found in compliance with this article and regulations adopted by  
7 the board.

8 (d) A license to compound sterile drug products shall not be  
9 issued or renewed until the board does all of the following:

10 (1) Reviews a current copy of the pharmacy's ~~policies and~~  
11 ~~procedures~~ *and policies* for sterile compounding.

12 (2) Reviews the pharmacy's completed self-assessment form  
13 required by Section 1735.2 of Title 16 of the California Code of  
14 Regulations.

15 (3) Is provided with copies of all inspection reports conducted  
16 of the pharmacy's premises, and any reports from a private  
17 accrediting agency, conducted in the prior 12 months documenting  
18 the pharmacy's operations.

19 (4) Receives a list of all sterile medications compounded by the  
20 pharmacy since the last license renewal.

21 (e) A pharmacy licensed pursuant to this section shall do all of  
22 the following:

23 (1) Provide to the board a copy of any disciplinary or other  
24 action taken by another state within 10 days of the action.

25 (2) Notify the board within 10 days of the suspension of any  
26 accreditation held by the pharmacy.

27 (3) Provide to the board, within 12 hours, any recall notice  
28 issued by the pharmacy for sterile drug products it has  
29 compounded.

30 (f) Adverse effects reported or potentially attributable to a  
31 pharmacy's sterile drug product shall be reported to the board  
32 within 12 hours and immediately reported to the MedWatch  
33 program of the federal Food and Drug Administration.

34 (g) The reconstitution of a sterile powder shall not require a  
35 license pursuant to this section if both of the following  
36 requirements are met:

37 (1) The sterile powder was obtained from a manufacturer.

38 (2) The drug is reconstituted for administration to patients by  
39 a health care professional licensed to administer drugs by injection  
40 pursuant to this division.

- 1     (h) This section shall become operative on July 1, 2014.

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